

EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
Document Format - Recommendation 5.1 Ver 1.5 5 March, 1997

Title: Electronic Document Format

Date: 5 March 1997

Background:

It is recognized that there is a need to exchange regulatory documents in a common interchange format. These documents may vary in size and complexity from simple correspondence to compound documents that include tables, graphics, etc..

Recommendation:

The Expert Working Group recommends the adoption of a standard interchange format that fulfills the following requirements:

- enables paper based information to be scanned into electronic format;
- retains the *content* and the *layout* of the original document;
- is both device and resolution independent;
- is designed for viewing and/or printing;
- allows the transfer of documents whose contents do not need to be modified or extracted into functional databases;
- allows the use of a viewer whose specifications are in the public domain.

Conditions:

None

Remarks:


The Expert Working Group has identified Portable Document Format (PDF) as a standard interchange format for electronic transfer of documents that meets these requirements:

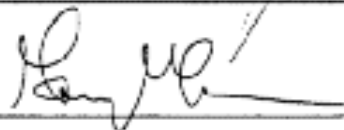
- It is recognized that PDF is a proprietary specification of Adobe Systems that has been placed in the public domain. It is a low cost solution which has become a de facto standard;
- The company (Adobe Systems) provides Acrobat Reader software free of charge for access and review of these documents;
- Many low cost plug-ins from numerous software providers are available to help sponsors create PDF format, hyperlinks, bookmarks etc., and reviewers to develop assessment reports with features like copy and paste, post-it notes, full text search etc.;
- Inclusion of hyperlinks and bookmarks facilitates browsing of documents;
- Certain documents are not currently appropriate for PDF transfer, e.g., X-rays, dynamic documents (susceptible to change), and multimedia etc..

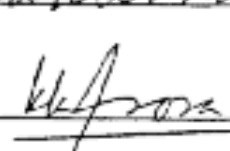
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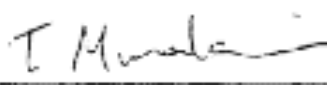
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